



External Research Request Application Information

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Definitions

Saginaw Chippewa Indian Tribe of Michigan – includes Saginaw Chippewa Tribal citizens, descendants, employees, other community members or affiliates, entities, assets, and intellectual property.

Research – is the use of systematic methods to gather and analyze information for the purpose of proving or disproving a hypothesis, evaluating concepts or practices or otherwise adding to knowledge and insight in a particular discipline or field of knowledge or to demonstrate or investigate theories, techniques or practices. Research includes but is not limited to the following:

- Basic and clinical research.
- Social, emotional, behavioral, and/or economic studies.
- Anthropological and archaeological studies.
- Community based research.
- Research on plants, animals, water, land, air, or weather.
- Cultural or historical research.
- Feasibility and other studies designed to develop, test and evaluate basic data in all phases of environmental and public health projects.

Projects or Activity – includes but is not limited to, recordings (audio, visual, and transcription recording by mechanical or manual means) of SCIT culture, or collaborative works with external partners.

Data – “information, especially facts or numbers, collected to be examined, considered and used to help decision-making, or information in an electronic form that can be stored and used by a computer” (Cambridge.org English Dictionary)

Information Sharing – the exchange of Information between two or more parties for a specific purpose (or purposes). The term “Information” is defined as any and all information, in whatever form (e.g. oral, written, digital, photographic (including video) and other formats). This includes, but is not limited to: statistics; Tribal program information; information regarding the Tribal community and/or community members; information collected on a specific topic by and/or for SCIT; Community Member and employee knowledge including cultural, historical, spiritual, ecological/environmental, and other types of knowledge; cultural works of art; any other types of information, data and/or knowledge shared with Data Recipient.

Multimedia – includes any product derived from SCIT intellectual resources of text, sound, song and images combined into an integrated product that can be transmitted and accessed interactively via digital machine – readable form or computerized network.

Publication – the dissemination of any information, data, or compilation, whether confidential, by any method or media, including verbal, written or electronic communications, and inclusive of periodic or final reports by a grantor.

Minimal Risk – the probability and magnitude of harm or discomfort anticipated in the requested research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vulnerable Subjects – Individuals who are incapable of protecting their own interests need to be informed, educated, and protected from risk in research. This includes but is not limited to pregnant women, fetuses, minors, mentally/physically/cognitively challenged, elderly, foster children, boarding school survivors, institutionalized, and individuals in an addiction treatment program. In the case of minors or cognitively impaired individuals, a parent or guardian must be informed. (Question for Legal- Where would we add protections for people that have passed on?)

Adverse Event – any untoward physical or psychological occurrence in a human subject participating in research. An adverse event can be any unfavorable or unintended event including abnormal laboratory findings, symptom or disease associated with the research or the use of a medical investigative test.

Policy

All research, projects, and activities involving the Saginaw Chippewa Indian Tribe will be reviewed and approved by the Data Governance Board and memorialized in a contractual agreement or permit. Research conducted must be beneficial, community-based, and consistent with SCIT priorities and concerns.

Procedure

The research/project application should include all of the following, as applicable to the project.

General Application Requirements

A. DGB External Application Form

B. Research Protocol / Project Description – Provide a summary in layman's terms of study design, research question, and procedures.

C. Study Design – Include research question, scientific methodology, length of study, and project description.

D. Research Procedures – Include all data/specimen collection, processing, and storage procedures. Include description of data collection source(s) (e.g. primary or secondary data).

E. Data Collection Instruments – Include all surveys and questionnaires (including interview guides and any other tools to gather information/data).

F. Recruitment Materials / Subject Information – Include copy of recruitment materials, a list of target population(s) and protections of participants. If vulnerable populations are involved, include description of additional safeguards for their protection.

G. Proposed Informed Consent / Parental Permission / Assent Form(s) - Include all consent and/or assent forms.

H. Confidentiality – Describe steps that will be taken to secure data collected and/or protect participant/tribal information. Describe if 'identifiers' will be obtained with data collection and remain with the data. Include who will have access to data collected.

I. Compensation – Describe if, how and when participants will be compensated.

J. Funding Source(s) – Please describe any funding sources for this project, and summarize the goals/objectives of the funded project.

K. IRB/RRB Review Process – All research projects must be reviewed and approved by a University, government, or other Institutional Review Board in addition to approval by the SCIT TRBB. Please indicate if your project has already received such approval (if so, include approval document), and if not, when you plan to seek approval, and which IRB/RRB Institution you will seek approval from. (Need to reword because not all projects will have IRB approval or seeking it)

L. Risks and Benefits to Individual Participants – Describe any risks to the participants. Describe any benefits to the participants (immediate, long-term, direct, indirect etc.).

M. Risks and Benefits to the Saginaw Chippewa Indian Tribe – Address any risks to the Tribal community and/or resources. Describe a plan to minimize risks to the Tribal community and/or resources. Describe the benefit to the Tribal community (immediate, long term, direct, indirect).

N. Results Dissemination – Include plans for sharing results with Tribal community.

Review Process

Primary Review

Full Board Review/Approval Process

The DGB is composed of nine members who will review external project requests during designated meetings with a minimum quorum. Project approval or disapproval is based on overall DGB consensus. SCIT Tribal Council will be provided with DGB recommendations for final approval of project.

Each research request will be logged for tracking purposes. Data Governance Board representatives will be provided with complete external request applications within 5 working days of submission. DGB members will use an Indigenous TRRB Scoring Matrix to evaluate requests and provide recommendations. DGB will provide applicants with written correspondence within 30 working days of complete external project request submission and review.

Approval – Project is approved as submitted.

Conditional Approval – Project is approved pending minor revisions agreed upon by DGB recommendation(s). Tribal Research Review Board TRRB will ensure that satisfactory changes were completed before commencement of the project.

Deferred for Substantive Issue(s) – Insufficient information is provided and/or substantial modification or clarification is required to adequately review application. Applications will be tabled pending receipt of additional information. Applicants will be notified of issue(s) by the Research Review group and have 30 days to submit sufficient information for reevaluation.

Disapproval – The DGB has determined the project does not benefit the Saginaw Chippewa Indian Tribe. Applicants will receive written correspondence as to why the project was denied.

Approval Period

Final project approval shall not be granted until all required application information has been received along with signed confidentiality and information sharing agreements.

Continuing Review

Active projects must be reviewed at least one time per year before the anniversary of the date of the initial approval. DGB may require more frequent review of projects that have been deemed a high risk on a case by case basis. The DGB retains the authority to discontinue projects if the project is noncompliant with DGB policies and procedures, or for any other reason consistent with the best interest of the Saginaw Chippewa Indian Tribe of Michigan.

Amendment of an Approved Project

The DGB requires prompt reporting of proposed changes to an approved project. Changes may not be initiated without board review and approval, except when necessary to eliminate immediate hazards to participants or others.

Adverse Event

Any adverse events must be promptly reported DGB within 24 hours of the occurrence. All project activities must cease pending DGB investigation.

Publication Review

All individuals wishing to publish products must submit a proposed manuscript to the Data Governance Board for review and approval prior to publication submission. The manuscript will be reviewed for technical content and validity, readability and organization of content, as well as assurance that the content aligns with SCIT priorities and concerns.

Enforcement

The Saginaw Chippewa Indian Tribe reserves the right to petition SCIT Tribal Court for any research, person, or entity that has been found in violation of the Saginaw Chippewa Indian Tribe's DGB policies/procedures. If found in violation, civil penalties may be awarded.

Acknowledgement

Enter initials here I have read and understand the terms the SCIT Data Governance Boards' External Research Request Application. I also understand all information gathered with the tribe and DGB approval solely belongs to the Saginaw Chippewa Indian Tribe of Michigan and any violations or unauthorized use of the tribe's information will result in penalties and fees for damages.

Enter initials here Yes I agree and understand this form Enter name here _____ electronic signature typed here